PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 520.154b [Amended]

4. Section 520.154b *Soluble bacitracin methylene disalicylate and streptomycin sulfate oral powder* is amended in paragraph (b) by removing ''011716'' and adding in its place ''062925''.

Dated: December 5, 1996.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 96–32067 Filed 12–17–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Carprofen Caplets

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Pfizer, Inc. The NADA provides for oral use of nonsteroidal anti-inflammatory carprofen caplets in dogs for relief of pain and inflammation. Carprofen has been shown to be clinically effective for the relief of signs associated with osteoarthritis.

EFFECTIVE DATE: December 18, 1996.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0614.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed NADA 141–053, which provides for oral use of carprofen caplets in dogs for the relief of pain and inflammation. Carprofen has been shown to be clinically effective for the relief of signs associated with osteoarthritis. The drug product is restricted to veterinary prescription use only. The NADA is approved as of October 25, 1996, and the regulations are amended by adding new 21 CFR 520.309 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning October 25, 1996, because no active ingredient (including any ester or salt thereof) of the drug has been approved previously in any other NADA.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 520.309 is added to read as follows:

§ 520.309 Carprofen caplets.

(a) *Specification*. Each caplet contains 25, 75, or 100 milligrams of carprofen.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. 1 milligram per pound of body weight twice daily. Caplets are scored and dosage should be calculated in half-caplet increments.

(2) *Indications for use*. For the relief of pain and inflammation in dogs. Carprofen has been shown to be clinically effective for the relief of signs associated with osteoarthritis in dogs.

(3) *Limitations*. The safe use of carprofen in pregnant dogs, dogs used for breeding purposes, or in lactating bitches has not been established. As a class, cyclo-oxygenase inhibitory nonsteroidal anti-inflammatory drugs (NSAID's) may be associated with gastrointestinal and renal toxicity. Patients at greatest risk for renal toxicity are those on concomitant diuretic therapy, or those with renal, cardiovascular, and/or hepatic dysfunction. Because many NSAID's possess the potential to induce gastrointestinal ulceration, avoid or closely monitor concomitant use of carprofen with other anti-inflammatory drugs, such as corticosteroids and NSAID's. Carprofen treatment was not associated with renal toxicity or gastrointestinal ulceration in safety studies of up to 10 times the dose in dogs. Do not use in dogs with bleeding disorders (e.g., Von Willebrand's disease). Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: December 6, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–32068 Filed 12–17–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

New Animal Drugs and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) from Pfizer, Inc., to Intervet, Inc.

EFFECTIVE DATE: December 18, 1996.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, has informed FDA that it has transferred ownership of, and all rights and interests in, approved NADA 140–857 (luprostiol sterile solution) to Intervet, Inc., P.O. Box 318, 405 State St., Millsboro, DE 19966. Accordingly, FDA is amending the regulations in 21 CFR 522.1290 to reflect the change of sponsor.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under

authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 522.1290 [Amended]

2. Section 522.1290 *Luprostiol sterile solution* is amended in paragraph (b) by removing ''000069'' and adding in its place ''057926''.

Dated: December 5, 1996.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 96–32072 Filed 12–17–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Propofol Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Mallinckrodt Veterinary, Inc. The NADA provides for intravenous use of propofol injection in dogs as an anesthetic.

EFFECTIVE DATE: December 18, 1996.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1616.

SUPPLEMENTARY INFORMATION: Mallinckrodt Veterinary, Inc., 421 East Hawley St., Mundelein, IL 60060, filed NADA 141–070, which provides for intravenous use in dogs of Rapinovet™ Anesthetic Injection (each milliliter contains 10 milligrams of propofol). The drug is used as a single injection to provide general anesthesia for procedures lasting up to 5 minutes, for induction and maintenance of general anesthesia using incremental doses to effect, and for induction of general anesthesia where maintenance is provided by inhalant anesthetics. The drug is limited to use by or on the order of a licensed veterinarian. The NADA is approved as of November 7, 1996, and the regulations are amended in 21 CFR part 522 by adding new § 522.2005 to reflect the approval. The basis of approval is provided in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for a 5-year period of marketing exclusivity beginning November 7, 1996, because no active ingredient (including any ester or salt of the active ingredient) of the drug has been approved in any other application under section 512(b)(1) of the act.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 522.2005 is added to read as follows:

§ 522.2005 Propofol injection.

(a) *Specifications.* The drug is a sterile, nonpyrogenic, oil-in-water emulsion containing 10 milligrams of propofol per milliliter.

(b) *Sponsor.* See No. 011716 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs.* (i) The drug is indicated for use as an anesthetic as follows: As a single injection to provide general anesthesia for procedures lasting up to 5 minutes; for induction and maintenance of general anesthesia using incremental doses to effect; for induction of general anesthesia where maintenance is provided by inhalant anesthetics.

(ii) The drug is administered by intravenous injection as follows: For induction of general anesthesia without the use of preanesthetics the dosage is 5.5 to 7.0 milligrams per kilogram (2.5 to 3.2 milligrams per pound); for the maintenance of general anesthesia without the use of preanesthetics the dosage is 1.1 to 3.3 milligrams per kilogram (0.5 to 1.5 milligrams per pound). The use of preanesthetic medication reduces propofol dose requirements.

(iii) Adequate data concerning safe use of propofol in pregnant and breeding dogs have not been obtained. Doses may need adjustment for geriatric or debilitated patients. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

Dated: December 6, 1996.

Stephen F. Sundlof,

Center for Veterinary Medicine.

[FR Doc. 96–32069 Filed 12–17–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 522 and 556

Animal Drugs, Feeds, and Related Products; Ceftiofur Sterile Powder for Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pharmacia & Upjohn Co. The supplemental NADA provides for intramuscular use in sheep of a reconstituted solution of ceftiofur sterile powder for treatment of sheep respiratory disease (pneumonia).

EFFECTIVE DATE: December 18, 1996.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1659.